UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

WYETH, Plaintiff, v. IMPAX LABORATORIES, INC.. Defendant.	Civil Action No. 06-222 (JJF) **PUBLIC VERSION**

IMPAX LABORATORIES, INC.'S CONSOLIDATED REPLY TO WYETH'S COUNTERSTATEMENTS

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I. Introduction

This Court's order governing summary judgment motions required Wyeth to file "a Counter-Statement certifying that genuine issues of material fact exist and setting forth the material facts the party contends are disputed." Instead, Wyeth filed what amounts to a pair of answering briefs, spending **sixty-four pages** arguing numerous pure issues of law instead of identifying material facts in dispute.

But it is no surprise that Wyeth was unable to identify any material *factual*, rather than legal, disputes: Impax's briefs cited nothing but Wyeth's own documents and the admissions of Wyeth's agents. Those undisputed facts, standing alone, are sufficient to support summary judgment. As set forth in greater detail below, Wyeth identifies no disputes of material fact precluding summary judgment.

II. Wyeth raises no genuine issues of material fact precluding summary judgment of anticipation.

In its motion for summary judgment, Impax argued that the Alza PCT application anticipates each claim of the '958 patent. The asserted claims of the '958 patent describe a "method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty-four hour period" by administration of an extended release formulation of venlafaxine. Those claims are infringed if the method is practiced. Likewise, because conduct which infringes after a patent issues anticipates if it occurs before the patent issues, *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1379 (Fed. Cir. 2003), those claims are anticipated by any prior art reference which enables practice of the claimed method.

Here, each limitation of the asserted claims of the '958 patent is anticipated by the Alza PCT application. For most limitations, this anticipation is express: for example, the PCT application explicitly describes "a method for delivering [venlafaxine] by administering a dosage form comprising 0.5 mg to 750 mg of the drug from a dosage form selected from sustained-release and controlled-release dosage forms in a therapeutically responsive dose over an extended period of time." Impax Ex. 22 (Alza PCT Application) at 26:12-16. In the case of

other limitations of the asserted claims, the PCT application anticipates inherently by disclosing a dosage form which, when administered according to the method set forth in the Alza PCT application, meets the remaining claim limitations, such as the limitations on Tmax.

That the dosage form disclosed in the PCT application inherently anticipates the Tmax limitations in the asserted claims when administered according to the method disclosed in the PCT application is proven by **REDACTED**. In its opposition, Wyeth quibbles with Impax's argument on two grounds: first, that the Tmax of **REDACTED** not in fact "about 6 hours," and second, that the formulation used in **REDACTED** was not taught by the PCT application. Neither of these issues precludes summary judgment.

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III. Wyeth raises no genuine issues of material fact precluding summary judgment of obviousness.

In response to Impax's argument that the patents in suit are obvious in light of the prior art, Wyeth purports to raise factual disputes regarding (1) reasonable expectation of success, (2) the predictability of the Tmax values recited in the claims, and (3) secondary considerations of non-obviousness, such as commercial success. Each issue Wyeth raises is either immaterial or not truly in dispute.

A. The factual disputes Wyeth identifies regarding reasonable expectation of success are immaterial.

The factual issues Wyeth raises regarding "reasonable expectation of success" are immaterial and legally irrelevant. Wyeth expends 14 pages arguing that a person of ordinary skill in the art would not have been certain to succeed at making an extended-release formulation meeting the claims. But that is not the legal standard. The Federal Circuit has been clear that "obviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007). "[A] rule of law equating unpredictability to patentability . . . cannot be the proper standard since the expectation of success need only be reasonable, not absolute." *Id.*

But throughout its brief, Wyeth attempts to do precisely what the Federal Circuit warned against in *Pfizer*, "equating unpredictability to patentability." Each of Wyeth's arguments is directed not toward the "reasonable expectation of success," but instead toward the irrelevant question whether success was predictable or unpredictable. For example:

- On page 23, Wyeth argues that "a researcher attempting to **predict** in 1996 whether an extended-release venlafaxine HCl formulation would be effective" faced "an **unpredictable** landscape."
- On pages 23 and 24, Wyeth asserts that because the "inefficiency and **unpredictability** of absorption" increases in the lower GI tract, colonic absorption of venlafaxine was "inherently **unpredictable**."
- On pages 25 and 26, Wyeth asserts that another biological mechanism "created **unpredictability**."
- On page 27, Wyeth asserts that researchers "could not **predict**" that an extended-release formulation of venlafaxine would be effective as a reuptake inhibitor of serotonin or noradrenalin in the brain.

Wyeth is attacking a straw man. Impax does not quibble with the proposition that there was some possibility Wyeth's development could have failed. But the law requires only a reasonable expectation of success. None of the purported factual disputes Wyeth raises are directed to that inquiry, and none refute the clear and convincing evidence Impax has presented showing that

Wyeth actually had, and a person of ordinary skill in the art would have had, a reasonable expectation of success.

Furthermore, Wyeth's arguments are so equivocal as to be meaningless. Merely because an attempt to create an extended-release formulation of venlafaxine *might* have failed means nothing about whether there was a reasonable expectation of success.

- If colonic absorption was insufficient, Wyeth argues, "an extended-release formulation might fail." D.I. 328 at 24.
- Because "P-pgp-mediated efflux might be saturable," Wyeth argues, efflux action could "hamper" the absorption of venlafaxine, so the drug "could in part fail to reach the bloodstream." *Id.* at 24-25.
- First-pass metabolism "may, in some cases, be saturable," and if so, bioavailability "could be reduced"– so "extending the release might therefore . . . have unpredictable consequences." *Id.* at 26.

The mere possibility of failure is irrelevant to the existence of a "reasonable expectation of success." This "evidence" raises no issues of material fact.

Finally, the after-the-fact expert opinion upon which Wyeth relies should be disregarded, as it directly contradicts to clear and convincing contemporaneous evidence from Wyeth itself. For example, Wyeth argues that "[a]s of March 1996, one of ordinary skill in the art could not have predicted or even estimated the impact on absorption resulting from extending the release of venlafaxine HCl." *Id.* at 23. But just nine pages later in the same brief, Wyeth quotes an internal Wyeth document

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. When Impax presents a dated Wyeth document **admitting**

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, Wyeth cannot use after-the-fact expert testimony to create a factual dispute.

Similarly, Wyeth's expert opines that as of March 1996, researchers "would have considered venlafaxine a poor candidate for an extended-release formulation." D.I. 328 at 26. But in Wyeth's

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C. Clear Federal Circuit precedent renders the secondary considerations of non-obviousness irrelevant in this case.

As Impax explained in its motion for summary judgment, the secondary considerations of non-obviousness are immaterial. The Federal Circuit has held that where, as here, "others were legally barred from commercially testing" an invention, the later commercial success of that invention has "no force" in the obviousness analysis. *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1376-77 (Fed. Cir. 2005). Wyeth does not dispute that its patent on the venlafaxine molecule meant that others were legally barred from commercially testing extended-release formulations of venlafaxine. That is the *fact* upon which the Federal Circuit's analysis in *Merck* turned, and the fact upon which Impax's argument relies. It is undisputed, and supports summary judgment.

IV. Wyeth raises no genuine issues of material fact precluding summary judgment of no written description.

Wyeth contends that this Court's claim construction opinion "dictates denial of Impax's motion" regarding written description. But this Court's decision to construe the claims broadly in fact bolsters Impax's argument that the specification does not reflect that the inventors had possession of "*the invention*, with all its claimed limitations," as required by *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479 (Fed. Cir. 1998). In the words of the specification, "**the invention comprises** an extended release formulation of venlafaxine hydrochloride comprising a therapeutically effective amount of venlafaxine hydrochloride in spheroids comprised of venlafaxine hydrochloride, MCC and, optionally, HPMC coated with a mixture of ethyl cellulose and HPMC." Impax Ex. 11 ('171 Patent) at Abstract (emphasis added). This Court has construed the claims to reach much more broadly than the inventors' description of "the invention" in the specification. The specification, for that reason, does not reflect that the inventors had possession of *the invention*, under this Court's claim construction.

Impax's argument is based entirely on the text of the specification, not on any disputed fact. Because "a patent can be held invalid for failure to meet the written description requirement, based solely on the language of the specification," *University of Rochester v. G.D.*

Searle & Co., Inc., 358 F.3d 916, 927 (Fed. Cir. 2004), the factual issues Wyeth raises are immaterial. Summary judgment on the issue of written description is not precluded by any factual dispute.

V. Wyeth raises no genuine issues of material fact precluding summary judgment of lack of enablement.

In its motion for summary judgment, Impax argues that, because the specification explicitly teaches away from REDACTED extended-release venlafaxine formulations, it cannot, as a matter of law, enable extended-release venlafaxine formulations **REDACTED** Impax relies only upon the text of the specification in making its motion. Wyeth does not even purport to contradict the facts on which Impax relies. While Wyeth cites the report of its expert, Dr. McGinity, it makes no factual argument. Wyeth wants the court to interpret the patent specification contrary to its plain language and differently from the way Impax presents them in its motion. In other words, Wyeth concedes the facts regarding the enablement issue are undisputed, but merely argues for a different legal conclusion. This cannot preclude summary judgment.

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These are the only facts upon which Impax relies, and they alone are sufficient to support summary judgment of lack of enablement. As Impax noted in its Motion for Summary Judgment, the Federal Circuit has held that a statements like Wyeth's which "discourages experimentation" renders the specification "inadequate as a matter of law." *AK*

Steel Corp. v. Sollac, 344 F.3d 1234, 1244 (Fed. Cir. 2003). Because Wyeth said in the specification **REDACTED** it cannot enable Impax's formulation, **REDACTED** Because this Court has construed the patents in suit to reach extended-release formulations containing any ingredients, the specification does not enable the claims' full scope, rendering the claims invalid. As the Federal Circuit stated in *AK Steel*: "Nothing further need be said about the matter." *Id.*

Here, as in *AK Steel*, the patentee has made an attempt to save his patent from summary judgment of no enablement by introducing expert testimony that one of skill in the art, reading the patent specification, would be able to practice the full scope of the claims even though the patent teaches away from certain embodiments. As the district court in *AK Steel* put it:

> The question is whether this expert report raises a genuine issue of material fact on the enablement issue. It is directly contrary to the specification which teaches that Type 1 aluminum will not work. Can an expert raise a genuine issue of fact on enablement by an opinion that one of ordinary skill in the art would have known that the process taught in the specification could have been modified to achieve results that the specification says cannot be achieved?

AK Steel Corp. v. Sollac, 234 F. Supp. 2d 711, 784 (D. Ohio 2002), *aff'd*, 344 F.3d 1234 (Fed. Cir. 2003). The district court, in a decision later affirmed by the Federal Circuit, answered in the negative: it held that expert opinion is insufficient evidence to create a factual dispute where the specification itself teaches away from the technique at issue. If the technique at issue "were so clearly with the skill of the art, it would have been expressly disclosed in the specification." *Id.* at 786 (quoting *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1367 (Fed. Cir. 1997)). Likewise, here, if **REDACTED** was so well-known in the art, it would have been expressly disclosed in the specification, rather than warned against **REDACTED** There is no disputed issue of material fact, and Impax is entitled to summary judgment.

VI. Wyeth raises no genuine issues of material fact precluding summary judgment of misjoinder of inventors.

Wyeth raises no genuine issue of material fact precluding summary judgment of misjoinder of inventors. Indeed, it does not take issue with any fact upon which Impax bases its

motion. Impax's motion is based on just two undisputed facts. *First*, Dr. Sheskey told Ms. Sherman to add HPMC to her granulation mix. Wyeth admits that this fact is not in dispute. *See* D.I. 329 at 12 ("[Sheskey] recommended that [Sherman] use the K grade of Dow's HPMC because it 'has a gel temperature of approximately 70-90C which would be well above your current manufacturing conditions.'"). *Second*, as the patents recount, the addition of HPMC "made production of spheroids practical." Impax Ex. 11 ('171 Patent) at 5:13.

These undisputed facts, standing alone, satisfy the standard set forth in *Pannu v. Iolab Corp.*, 155 F.3d 1344 (Fed. Cir. 1998), which Impax discussed in its brief.

Wyeth's attempt to create a dispute of material fact by injecting additional, irrelevant expert testimony into the inquiry is unavailing. The undisputed evidence shows that Dr. Sheskey's contribution "made production of spheroids practical." If the formulation work was inventive, as Wyeth contends, Dr. Sheskey, who made a crucial contribution to the formulation claimed in the patents, must be one the inventors. No factual disputes preclude summary judgment of misjoinder of inventors.

VII. CONCLUSION

As set forth above, Wyeth's counterstatement raises no genuine issues of material fact that would preclude summary judgment.

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